

**FIFTH**  
**INFORMATION DISCLOSURE**  
**STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 1

Application Number	10/551,205
Filing Date	November 14, 2006
First Named Inventor	Nicholas Bodor et al.
Examiner Name	JONATHAN S LAU
Attorney Docket No.	0056192-000024

**U.S. PATENT DOCUMENTS**

Examiner Initials	Document Number-Kind Code	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Figures Appear
	US-			
	US-			
	US-			
	US-			
	US-			
	US-			
	US-			
	US-			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Foreign Patent Document	Publication Date (MM-DD-YYYY)	Name of Patentee or Applicant of Cited Document	STATUS						
	Country Code <sup>1</sup> , Number, Kind Code			Translation	Partial Translation	Eng. Lang. Summary	Search Report	IPER	Abstract	Cited in Spec. / Pg. No(s).

<sup>1</sup>Enter Office that issued the document, by the two-letter code.

**NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	VAN AXEL CASTELLI et al. "Characterisation of an Inclusion Complex Between Cladribine and 2-Hydroxypropyl- $\beta$ -Cyclodextrin," <i>J. Pharm. Sci.</i> , Vol. 97, No. 9, September 2008, pp. 3897-3906, Wiley InterScience and the American Pharmacists Association, US
	<i>Drugs.com</i> , "Oral Investigational Treatment Cladribine Tablets for Multiple Sclerosis Significantly Reduced Relapse Rate in Phase III Pivotal Trial," accessed online February 3, 2009, at <a href="http://www.drugs.com/clinical_trials/oral-investigational-cladribine-multiple-sclerosis">http://www.drugs.com/clinical_trials/oral-investigational-cladribine-multiple-sclerosis</a>
	"Serono's Oral Cladribine for the Treatment of Multiple Sclerosis Awarded Fast Track Status by FDA", accessed online February 3, 2009 at <a href="http://prnewswire.com">http://prnewswire.com</a>
	Merck Serono News Release, "Two-year Phase III Data Presented at AAN 61st Annual Meeting Show Positive Outcome of Cladribine Tablets in Patients with Multiple Sclerosis", April 29/30, 2009, available online.

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.